



Bathless Disintegration System

3106

3104

3102

Operation Manual

Bathless Disintegration Systems - Model 3106, 3104 and 3102

Operation Manual

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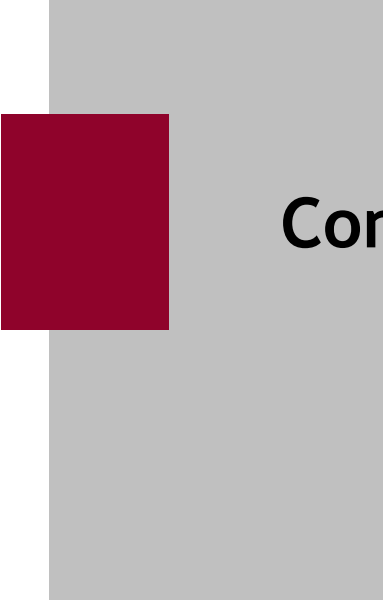
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Document Revision History

Rev	Date	Notes
A	11/21/03	Initial Release (See CN 0408)
B	9/20/05	Removed Certificate of Compliance from Manual. Certificate is a separate file included with the Manual CD. See Change Notice 0515. Page 3-9: Step #7 - change “led” to “LED” and “no” to “number” Page 3-9: Add to Step #8 - “Wait at least one minute for the temperature reading to stabilize in the beaker as the baskets agitate the water.” Page 3-9: Under “Scan Mode” - change “display” to “displaying” Page 3-11: Under “Beginning a Test” Step #2 - change “beaker” to “basket” Page 3-11: Under “beginning a Test” Step #3 - change “2 minutes” to “70 seconds” Page 3-11: Add new section “Viewing Tablets During a Test” after “Viewing Information During a Test” Page 5-2: Last line of table - change “Err 15x” to “Err 16x” Page A-1: Removed Part “Cover for Basket Assembly”
C	11/15/06	See CN #0563. Added CE Certificate of Conformance and minor changes.



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About this Manual

About This Manual includes information about what is contained in this manual and the conventions used.

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Purpose

This manual covers the installation, routine operation, maintenance and repair of your Model 3106, 3104 or 3102. It has information regarding the commands, menus, indicators and controls. Please read Chapters 1, 2 and 3 before you operate the instrument.

Audience

This manual is written for any person responsible for maintaining, operating or troubleshooting the Distek Model 3106, 3104 or 3102.

Contents

Chapter 1 - Introduction	Provides a general overview of the instrument.
Chapter 2 - Installation	Describes how to unpack and properly install and qualify the unit.
Chapter 3 - Operation	Describes the operation of the unit.
Chapter 4 - Maintenance	Explains the steps necessary to maintain the unit.
Chapter 5 - Troubleshooting	Provides a troubleshooting chart and description of error messages to assist the user if a problem should arise.
Appendix A - Spare Parts and Accessories	Provides a table of recommended and optional spare parts.
Appendix B - Pre-Installation Considerations: Electrical Power Supply	Recommendation information pertaining to electrical power supply.

Appendix C - CE Declaration of Conformity	CE Declaration of Conformity certificate.
Appendix D - Certificate of Compliance	Certificate of Compliance
Appendix E - Sample Printouts from Parallel Printer	Sample printouts for a parallel printer.

Prerequisites

This manual assumes that you have an understanding of the principles of disintegration testing.

Documentation

This manual contains important information regarding the safe operation and maintenance of your Distek Model 3106, 3104 or 3102.

Conventions

The following table contains Warnings, Cautions and Notes that are used throughout the document for your protection. Please read this section before using the instrument.

	“WARNING” statements are used in this manual to prevent injury to personnel or equipment.
	“CAUTION: Risk of Electric Shock” statements are used to prevent injury when high voltage is present.
	“CAUTION” statements are used to prevent damage to equipment.
	“NOTES” contain helpful information.

REQUIRED

ACTION

“REQUIRED ACTION” is used where necessary to distinguish the action needed from Warnings, Cautions and Notes.



1 Introduction

This chapter provides an overview of the unit and system specific specifications.

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Overview

Distek advances disintegration testing by incorporating bathless technology with the Model 3106, 3104 and 3102 Bathless Disintegration Test Systems. The systems use the latest in bathless heating to offer a disintegrator without the mess and drawbacks associated with conventional water bath-based instruments. The Distek 3106, 3104 and 3102 Bathless Disintegration Systems consist of a motion control and a temperature control system varying from two to six positions. The system has intelligent programming features that allow automatic control of end of test, comprehensive method reporting and validation.

Specification

Requirements	Description
Disintegration Beakers	6 built-in beaker positions (2 or 4 optional)
Volume	Up to 900 mL
Drive Positions	6 standard (2 or 4 optional)
Display	Dot Matrix and LED display
Basket Stroke	30 Cycles per Minute, 5.5 cm
Accuracy	29-32 Cycle per Minute
Timer Ranges	1 min. to 99 hr. 59 min. 59 sec.
Timer Resolution	1 sec.
Temperature Control	Solid State Heating Elements
Temperature Range	20°C to 45°C
Display Resolution	0.1°C
Temperature Accuracy	±1.0°C
Motor	High Torque, Permanent Magnet
Program Mode	Automatic
Interface Ports	Parallel Printer, RS-232
Construction Materials	Aluminum, Stainless Steel & Engineering Plastics
Dimensions	25"(W) x 21"(H) x 21"(D) (64cm x 53cm x 53cm)
Net Weight (Approx.)	48 lb. (21.8 kg)
Electrical Power	115V 50/60Hz 15A or 230V 50/60Hz 8A (Operating voltage pre-set at factory)

Physical Site Considerations

The dimensional requirements specified below are adequate for the installation of the Bathless Disintegration System:

1. The minimum bench depth (front edge of bench to the back splash or wall) needed is 21" (53cm). However, the minimum recommended bench depth is 23" (58cm).
2. The minimum linear bench space requirement is 25" (64cm). Distek recommends that at least 29" (74cm) be allocated whenever manual operations are required to be performed adjacent to the system.
3. There must be no obstruction (cabinet, shelf, or outlet) that intrudes into the minimum footprint of the unit up to a height of 22" (56cm) above the bench surface where the unit is to be installed.
4. The bench must be capable of sustaining the weight of the unit and all of its accessory parts without significant bending. Because the entire mass of the unit is transferred to the bench surface through circular padded feet, the bench surface should be strong enough to withstand the entire weight of the unit (including beakers full of media).
5. The bench slope should be less than 0.75" (1.9cm) from front to back or from side to side over the unit's foot print.

Environmental Considerations

Ambient Laboratory Temperatures



Distek recommends that the laboratory temperature control system fans be kept on at all times. This should improve set point control, and minimize short-term excursion range.

Maximum Conditions:

1. To achieve the full range of controlled operation (30°C to 45°C) within specified tolerances the Bathless Disintegration Systems are designed to be installed and operated in laboratories where the maximum operating temperature does not exceed 25°C.
2. The maximum allowable ambient operation temperature is 30°C.



Operating environments above 25°C limit the range for satisfactory operation of system to between 35°C and 45°C.

Minimum Conditions:

To assure controlled operation within specified tolerances, the system is designed to be operated in laboratories where minimum operating temperatures do not drop below 15°C.

Variability or Short Term Fluctuations:

To assure controlled operation within specified tolerances, the system used to control the temperature of the laboratory where the system is installed must be able to maintain the ambient air temperature within $\pm 2.5^\circ\text{C}$ of set point (worst case).

Thermal Loading:



For laboratories where temperature control is critical, installation of several disintegration units may require that the system be re-balanced. Thermostats may need to be relocated to maintain temperature uniformity in the lab.

1. Each unit contributes an average thermal load of about 0.6 kW when operating. The lab's cooling systems must have sufficient excess cooling capacity to handle the aggregate thermal load for all systems installed.
2. The heating system must also be able to respond to the increased loading from the units by appropriately throttling back.

Ambient Laboratory Humidity



Distek recommends that the laboratory humidity control system fans be kept on at all times if possible. This should result in better set point control and reduce the short term excursion range.

Maximum:

The Bathless Disintegration System may add to the humidity of the laboratory during operation. The bathless design reduces humidity compared to other models, but any positions filled and left uncovered can raise humidity levels. Water vapor and/or hydrogen chloride vapor, from dissolution media, can cause serious effects when condensed on electrical components and contacts. The lab's environmental controls should maintain the humidity level below the dew point, to minimize the risk of condensation.

Minimum:

The Bathless Disintegration System utilizes solid-state semiconductor devices. It is important that the humidity level be kept at or above 30% relative humidity, to minimize the risk of damage to control circuits caused by static discharge.

Air Quality Considerations

Distek disintegration systems are designed to be operated in a lab environment that has no visible dust problem, and with organic solvent vapor levels as low as possible. Operation is not recommended in dusty lab environments, or in labs with significant chlorinated or reactive solvent vapor levels. These dust or vapor levels may have serious effects on system components. Absorption of vapors into disintegration media may bias test results. Some disintegration tests may require disintegration and drug release media prepared from USP quality water. Absorbed vapors may cause difficulty in complying with USP requirements.

Operation Warnings and Notes



For your safety, the information in this manual must be followed to minimize the risk of fire or explosion, electrical shock, or to prevent property damage, personal injury or loss of life.



Use this equipment only for its intended purpose as described in this Operation Manual. Never attempt to operate this instrument if it is damaged, malfunctioning, partially disassembled, or has missing or broken parts, including a damaged cord or plug.



Improper servicing or adjustment practice can cause equipment failure or serious physical injury. This equipment must be adjusted and serviced by qualified electrical maintenance personnel who are familiar with the construction and operation of the equipment and the hazards involved. Take diligent care during adjustment. All exposed points on the control circuit boards are electrically hot with respect to earth ground.



HIGH VOLTAGE IS EXPOSED WHEN THE REAR PANEL IS OPENED ON THE DISINTEGRATION SYSTEM. Dangerous voltages exist on the circuit boards when powered. Disconnect AC power from the system while troubleshooting. Be alert. High voltage can cause serious or fatal injury.



All Bathless Disintegration System heaters have thermostatic protection. In the event of a malfunction (or if no liquid in beaker), the heater will cut off at approximately 150°C. Thermostat automatically resets after cooling down.



Take proper precautions when handling disintegration media. Liquid in beaker may be HOT. Wear splash protection to avoid exposure to scalding, acidic, caustic, or pharmaceutical hazards. Bacteria have been shown to thrive in certain media, especially at test temperatures.

	The heating of aggressive media can cause explosion, implosion, release of toxic or flammable gases. Appropriate cautions should be taken.
	The Bathless Disintegration Systems are capable of utilizing all of the commonly used disintegration media such as 0.1 HCL, phosphate buffers and sodium lauryl sulphate.
	In the event of a hazardous material spill on the external surface of the instrument, the unit can be cleaned with a disposable cloth or paper wipe, then rinsed and dried with water. The same approach can be used for internal spill but the power must be disconnected first!
	Before using any cleaning or decontamination method recommended by the manufacturer, users should check with the manufacturer that the proposed method will not damage the equipment.
	Heater surfaces may be HOT. Do not touch beaker heater assemblies when the system is in operation. Injury may result.
	Improper remote PC control of the system may lead to unexpected motor and/or heater operation.
	To avoid glass breakage and injury: • Do not heat beaker empty. • Do not clean with materials that scratch. • Do not bump. Discard beakers if cracked, scratched or excessively heated empty.
	Avoid powering on and preheating multiple units simultaneously. Such conditions may induce a current surge.

	• DO NOT OPERATE THE BATHLESS DISINTEGRATION SYSTEMS WITH LESS THAN 500mls LIQUID IN EACH BEAKER. • USE ONLY GLASS BEAKERS SUPPLIED FOR THE SYSTEM BY DISTEK.
To Avoid Damaging The Instrument:	

- **CONNECT THIS UNIT TO THE SPECIFIED AC SUPPLY. OBSERVE PROPER GROUNDING.**
- ♦ **FAILURE TO OBSERVE THESE PRECAUTIONS MAY DAMAGE THE HEATER ASSEMBLIES AND/OR BEAKERS.**



The Bathless Disintegration Systems are supplied with proper heaters and settings for the specified operating voltage (see label for information). Do not attempt to convert unit to another mains supply without contacting Distek's factory first!



Take care when removing or replacing beaker heaters. Turn off unit and disconnect power from the system. Do not use metal tools or sharp objects to mount heater. Heater failure and/or injury could result.



External cables (excluding power cable) are limited to less than 3 meters length in order to maintain electromagnetic compliance.



Some forms of electromagnetic interference may cause unexpected operation. If this occurs, the unit will return to normal operation once the interference is removed.

General Instrument Overview

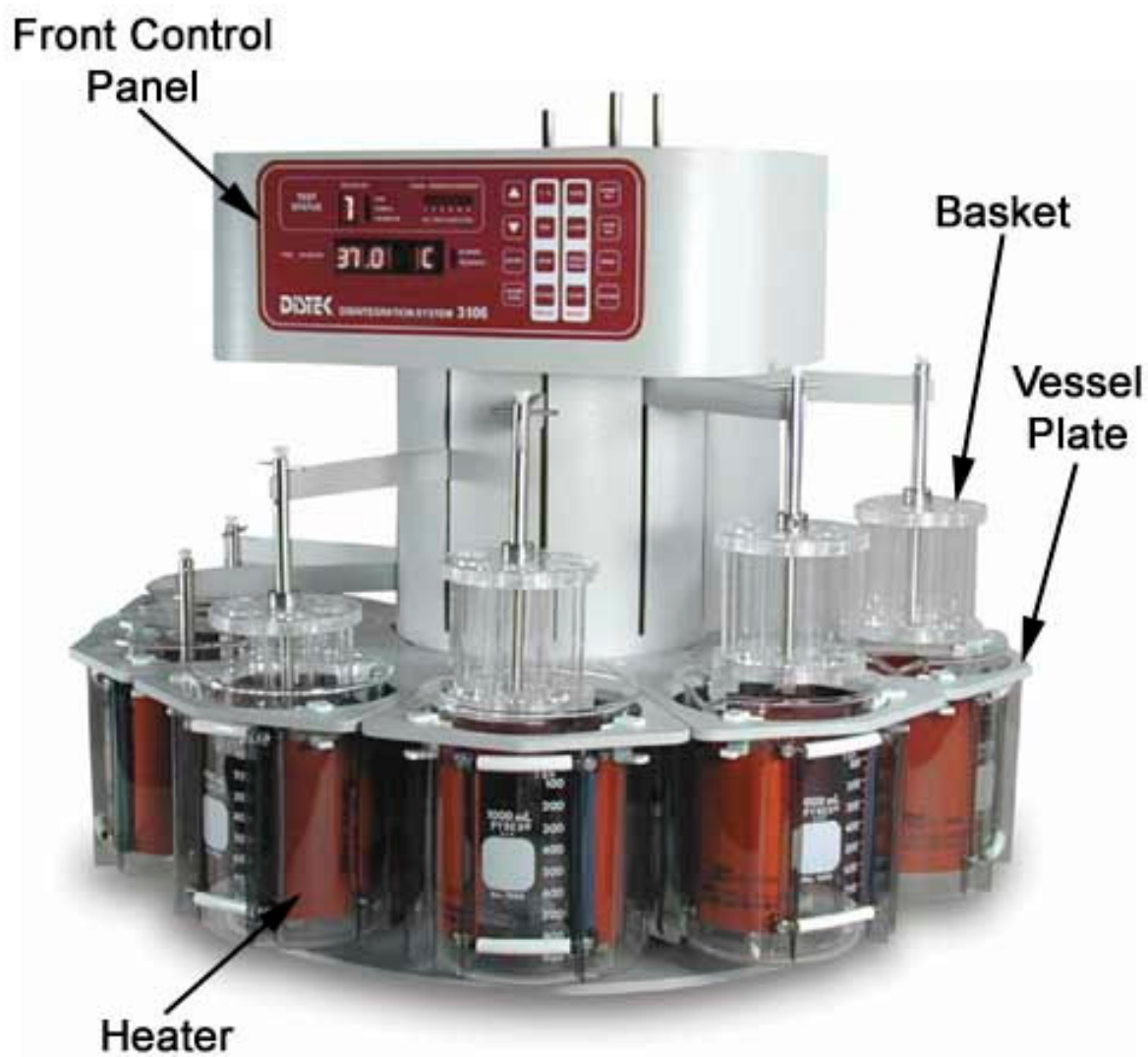


Figure 1-1: Bathless Disintegration Systems (3106 Shown)



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Installation

This chapter describes the steps necessary to properly unpack and install the instrument.

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Unpacking

Please take a few moments when unpacking the Distek Bathless Disintegration System to check for all items indicated on packing list. Notify DISTEK or your shipper immediately of any discrepancies or damage to cartons or contents in transit.



To avoid injury, two people should remove the system from its carton.

Packing must be removed before operating this instrument. To remove packing:

1. Cut through the tape at the top of the carton. Open the four top flaps.
2. Open the large carton.
3. Carefully remove packing insert.
4. Slide or lift the system out of its packing carton.
5. Remove all packing materials.

Placing the System on the Benchtop



Connect this unit to the specified AC supply. Observe proper grounding.

1. Trained personnel (2 people) should lift the unit onto the bench and slide it into position.
2. Connect the unit to the specified AC supply.

Positioning the Beakers

To install beaker in heater assembly:

1. Slide the beakers gently down through the clips into the heater jackets.
2. The beakers should stop on the white clips located on the beaker plate and should not require excessive force. Installing the beaker too low can prevent the basket from reaching the specified depth.

Disintegration Baskets



Test media must be poured into the beaker prior to placing the baskets on the hanger, otherwise the basket will need to be removed from the hanger to pour liquid into the beaker.



Do not grasp the baskets by their glass tubes when installing or removing. Always grasp baskets by the 'tee' handle at the top of the shaft.

Installing the baskets:



Figure 2-1: Basket Installation

1. Lift the basket with first and second fingers under the horizontal rod shown in Figure 2-1.
2. Press down on the white button with your thumb while sliding the basket onto the hanger.

3

Operation

The chapter describes the user interface screens and system administration for the instrument. It also provides step-by-step instructions to perform many common tasks.

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Control Keypad

The control keypad is shown in Figure 3-1:

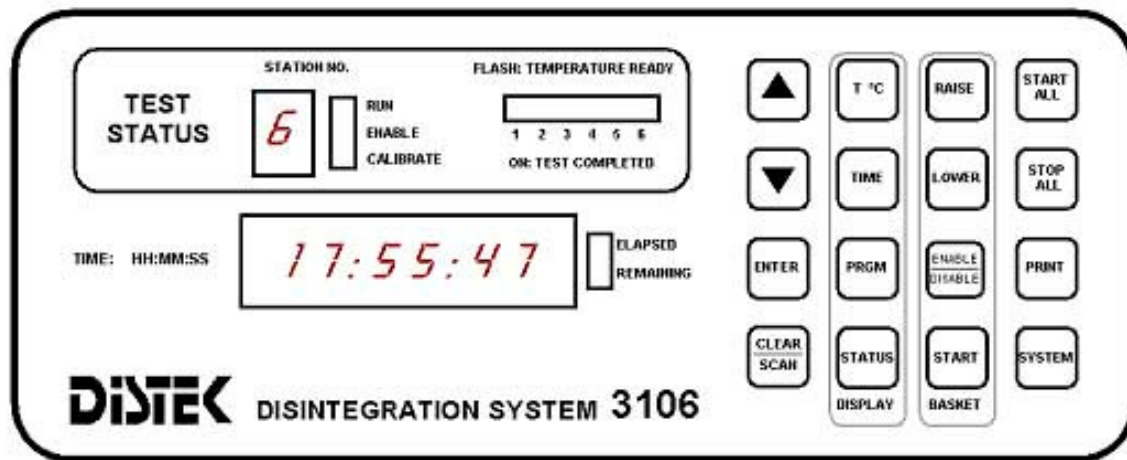


Figure 3-1: Control Keypad

The function of the buttons is as follows:

Arrow Keys

The arrow buttons are used throughout the user interface to change certain values such as test temperature, test time, etc... They are also used to scroll through the station numbers.

Enter

This button is used to accept values that have been entered.

Clear/Scan

This button is used to enter scan mode which allows the unit to scan through all station numbers and display the positions relevant data (temperature, time, etc...). The button can also be used to cancel certain actions.

Display Buttons

This set of 4 buttons controls what information is displayed on the unit.

T°C

Selecting this button will display the active station number's temperature.

TIME

Selecting this button will display the active station number's test time setting.

PRGM

This button will enter into program mode to setup test parameters (temperature and time).

Status

This will display the stations status: Preheat, Ready, Running or Idle.

Basket Buttons

These four buttons are used to control certain basket actions.

Raise

This button will raise the active station number basket.

Lower

This button will lower the active station number basket.

Enable/Disable

This button will either enable or disable the active station number.

Start

This button will start the active station number assuming that station is enabled.

Start All

This button will start the test for all enabled stations.

Stop All

This button will stop the test for all stations currently running.

Print

Depending on the status of the system, pressing this button will produce one of three printouts:

- While in scan mode, it prints out the test result of the last completed test showing data for all enabled positions.
- When not in scan mode, it prints out the test result of the last completed test showing data for only the active positions.
- While in calibration mode it prints out the temperature calibration data.

System

The system button is used to enter into system mode. To enter this mode, press the system button while the unit is starting up (DISTEK will be display on the screen).

Test Status

This area of the display contains information about the active station and its status.

Station No. and LEDs

The station number indicates which beaker's status and time or temperature is being displayed.

The ENABLE LED indicates when the displayed station's heater is enabled.

The RUN LED indicates when the displayed station is running a test.

The CALIBRATE LED is enabled during temperature calibration.

Flash: Temperature Ready/On: Test Complete

A flashing LED indicates that the temperature is stable at the set point and ready to begin the test for that particular station number.

A continuously lit LED indicates the test for that station number has been completed.

Time/Temperature Status

The temperature (°C), elapsed or remaining test time are shown for the displayed station number.

System Administration - System Mode

The system button provides access to modify such features as beep mode, unit address, etc...

There are two methods to enter and exit system mode.

Method 1: The system is turned off.

1. Turn the power on.
2. While the system is booting up press the **SYSTEM** key when 'DISTEK' is shown on the display.
3. When all configurations are complete press **CLEAR/SCAN**.

Method 2: The unit is powered on.



The system must be in Scan Mode. See Scan Mode on page 3-9 for more information.

1. Press the following key sequence:
SYSTEM → T°C → LOWER → PRGM → START → ENTER
2. When all configurations are complete press **CLEAR/SCAN**.

Audible Beep Configuration

When in system mode the first option displayed is 'BEEP'. This lets the user turn the audible beep on or off.

1. Press **ENTER**.
2. Use the **UP ARROW** to set the option of 'ON' and the **DOWN ARROW** for 'OFF'.
3. Press **ENTER** to move to the next option.

Setting the Time and Date

The next option will be 'TIME' setup. The time feature scrolls through the following options in this order:

Day (DD) → Month (MO) → Year (YY) → Hour (HH) → Minutes (MM)

1. Press **ENTER** to display 'DD: 00'.
2. Press **PRGM** to modify the day value or the **UP ARROW** to move to the next option.
3. Use the **ARROW** keys to change the day.
4. Press **ENTER** to display 'MO: 00'.

5. Press **PRGM** to modify the month value or the **UP ARROW** to move to the next option.
6. Use the **ARROW** keys to change the month.
7. Press **ENTER** to display 'YY: 00'.
8. Press **PRGM** to modify the year value or the **UP ARROW** to move to the next option.
9. Use the **ARROW** keys to change the year.
10. Press **ENTER** to display 'HH: 00'.
11. Press **PRGM** to modify the hour value or the **UP ARROW** to move to the next option.
12. Use the **ARROW** keys to change the hour.
13. Press **ENTER** to display 'MM: 00'.
14. Press **PRGM** to modify the minute value or the **UP ARROW** to move to the next option.
15. After all options have been set press the **ENTER** key to exit 'TIME' setup.

RS-232 Setup

This option configures the line feed option for the RS-232 communication protocol.

1. While in the system mode use the **ARROW** keys until 'RS232' is displayed.
2. Press **ENTER**.
3. Use the **UP ARROW** to select 'S1 Cr/Lf' or the **DOWN ARROW** to select 'S1 Cr'. (Cr is carriage return and Lf is line feed.)
4. Press **ENTER** to exit.

Printer Setup

This option allows the user to turn a line feed on or off during printing.

1. While in the system mode use the **ARROW** keys until 'PRINTER' is displayed.
2. Press **ENTER**.
3. Use the **UP ARROW** to select 'P1-Cr/Lf' or the **DOWN ARROW** to select 'P1-Cr'. (Cr is carriage return and Lf is line feed.)
4. Press **ENTER** to exit.

Changing the Unit Address



The default factory set I/O address is 16.

The 'UNIT ADD' setting allows the user to change the unit's address if necessary.

1. While in the system mode use the **ARROW** keys until 'Unit Add' is displayed.
2. Press **ENTER**.
3. Use the **UP ARROW** to change the address.
4. Press **ENTER** to exit.

Temperature Calibration

Accurate calibration of the temperature sensors is essential for proper operation of the Distek Bathless Disintegration Systems. Factory calibration provides accuracy within $\pm 1.0^{\circ}\text{C}$. Care must be taken when re-calibrating in the field, in order to realize the full accuracy and range of the temperature sensing system.

All installed temperature sensors are factory-calibrated using an NIST-traceable digital reference thermometer, the Distek TempChek. Distek recommends a 6-month calibration cycle, during which each sensor is checked and adjusted by this method to the specified accuracy. Only qualified personnel should adjust the unit's calibration.

Interim temperature checks should be executed by verifying and recalibrating each beaker temperature when compared with TempChek or any calibrated thermometer.

The Bathless Disintegration System will automatically detect whether a High-Temperature Calibration or a Low-Temperature Calibration will be performed based on the temperature of the sensor. If the temperature of the sensor is below 25°C and 15°C below the last high-temperature calibration a Lo-Cal will be performed. If the temperature of the sensor is above 25.05°C and 15°C higher than the last low-temperature calibration a Hi-Cal will be performed. Use 700-1000ml water in each beaker. It is suggested to use cool water between 18°C and 22°C to perform Low-Temperature Calibration and warm water between 38°C and 42°C to perform High-Temperature Calibration. There must be a difference of at least 15°C between the Lo-Cal temperature and the Hi-Cal temperature in order for the calibration procedure to work properly.



Verify accuracy of low temperature calibration (18°C - 22°C) before performing High-Temperature Calibration.

In order to stabilize beaker temperature during the calibration procedure, the heaters are automatically turned off when the Calibration screen is accessed. This prevents the high-powered heaters from raising temperatures rapidly.

Calibration Procedure Using a Distek TempChek or a NIST-Traceable Reference Thermometer

1. Fill each beaker with 900mls of media.
 - a. For a low temperature calibration, media should be between 18°C and 22°C.
 - b. For a high temperature calibration, media should be between 38°C and 42°C.
2. Install the basket on each position.
3. Enter system mode as described in the System Administration section on page 3-6.
4. Use the **ARROW** keys until CAL appears on the display.
5. Press **ENTER**.
6. Using the **ARROW** keys to navigate to position 1.
7. Press the **PRGM** button. The calibrate LED next to the station number should be illuminated.
8. Place a Distek TempChek or NIST-traceable reference thermometer into position one. Wait at least one minute for the temperature reading to stabilize in the beaker as the baskets agitate the water.
9. Using the **ARROW** keys set the temperature of the position equal to the external thermometer.
10. Press **ENTER**. An audible beep will sound confirming the calibration.
11. Repeat steps 6 through 10 for the remaining beakers.

Operating the Disintegrator

1. Turn on the power using the power switch located at the right rear of the instrument. The display will read 'DISTEK'.
2. After approximately 5 seconds, the unit will enter scan mode (scrolls through all station numbers displaying their temperatures).

Scan Mode

When the unit initially powers up it will automatically enter Scan Mode. Scan mode will scan through all the station numbers displaying either the temperature or time of the active station depending on which parameter is selected (press the **T°C** or **TIME** button to toggle between the two values).

Pressing the **ENTER** or **ARROW** keys will exit out of Scan Mode.

Individual Station Mode

When the unit is not in scan mode it will be in Individual Station Mode. This mode will display the value for the active station number. To change station numbers use the **ARROW** key to move to the different stations.

Setting Beaker Temperature and Test Time for Individual Positions

1. If in Scan Mode (see Scan Mode on page 3-9) press the **UP** or **DOWN ARROW** keys to exit this mode.
2. Scroll to the desired basket position using the up or **DOWN ARROW** keys.
3. To set beaker temperature press the **PRGM** button. The temperature set point will flash.
4. Raise or lower the set temperature using the up or **DOWN ARROW** keys.
5. Press the **TIME** button.
6. Raise or lower the test time using the up or **DOWN ARROW** keys.
7. Press **ENTER** to accept the values.

Setting Beaker Temperature or Test Time for All Positions

1. If in Scan Mode (see Scan Mode on page 3-9) press the **UP** or **DOWN ARROW** keys to exit this mode.
2. Press the **PRGM** button twice. Station number '0' will be displayed and the temperature set point will flash.
3. Raise or lower the set temperature using the up or **DOWN ARROW** keys.
4. Press the **TIME** button.
5. Raise or lower the test time using the up or **DOWN ARROW** keys.
6. Press **ENTER** to accept the values.

Enabling All Positions

1. Press the **CLEAR/SCAN** button to enter Scan Mode.
2. To activate or deactivate all positions press the **ENABLE/DISABLE** button. Observe the ENABLE LED illuminate next to the station number on the display.

Starting Pre-heating

1. To preheat a particular beaker select the station number and press **START**.
2. To preheat all *enabled* beakers press **START ALL**.

Beginning a Test



Preheat must be complete prior to starting test.

1. Select which station to begin by setting this station as the active position using the **ARROW** keys.
2. Press the **RAISE** button to raise the basket.
3. Introduce tablets within 70 seconds.
4. Press the **LOWER** button to lower the beaker and begin the test.
5. Repeat steps 1-4 for the remaining positions.

Viewing Information During a Test

Information such as temperature, time (both remaining and elapsed) and test status can be viewed while a test is running. These values can be viewed while the instrument is in Scan Mode or Individual Position Mode.

1. While a test is running set the unit to Scan Mode (pressing the **CLEAR/SCAN** button will enable the instrument to scan through all station numbers) or Individual Position Mode (using the **ARROW** key to view data on specific stations only).
2. Press the **T ° C** button to display the current temperature.
3. Press the **TIME** button to display the test time information. Pressing the **TIME** button repeatedly will toggle between elapsed and remaining time (notice the ELAPSED and REMAINING LEDs next to the time illuminate).
4. Press the **STATUS** button to view the test status. The options are Preheat, Ready, Running and Idle.

Viewing Tablets During a Test

1. While a test is running select which station to view by using the **ARROW** keys.
2. Press the **RAISE** button to raise the basket for viewing of the tablets. Note: The basket must be lowered within 70 seconds or the test will automatically be aborted.
3. Press the **LOWER** button to continue the test.

Aborting a Test

If a test is running it is possible to abort all stations or individual positions.

Aborting All Stations

1. While a test is running press **STOP ALL**. The screen will flash 'ABORT?'.
2. Press **ENTER** to abort or **CLEAR/SCAN** to return to the test (cancel).

Aborting Individual Stations

1. While a test is running use the ARROW keys to select the station to abort.
2. Press **ENABLE/DISABLE**. The screen will flash 'ABORT?'.
3. Press **ENTER** to abort or **CLEAR/SCAN** to return to the test (cancel).

Shutting Unit Off

1. Make sure all heaters are off and all baskets are raised. Pressing **STOP ALL** will abort any test currently running.
2. Shut down the unit using the On/Off switch located in the lower right rear of the unit.

Printouts

The Bathless Disintegration System contains several preformatted printouts. The unit is capable of printing data for all position from the previous test, data for individual positions from the last test and calibration data. Information such as test settings, vessel temperature results, DPM results, etc... is displayed on the printout. See Appendix D for sample printouts.

Pressing the **PRINT** button while in Scan Mode will print data from all positions from the previous test. While in Individual Station Mode pressing the **PRINT** button will print data for the active station from the previous test.

Pressing the PRINT button while in Calibration Mode will print calibration data. See Temperature Calibration for more information on Calibration Mode.

To configure printing simply connect a printer cable from a printer to the printer port located on the side of the system.

Serial Port Control

Command	Response	Function
[CONT:VESL:TEMP?]	[x- <i>nnn</i> ,...] / [Temperature set point reading fails?]	Read the temperature set point of all positions
[CONT:VESL:TEMP x- <i>nnnn</i>]	[x- <i>nnnn</i> !] / [Invalid value?] / [Temperature set point change fails?]	Change the temperature set point of position x to <i>nnnn</i>
[CONT:MOTO:SET?]	[<i>nnn</i>]	Check the main motor set RPM
[CONT:MOTO:STAT?]	[ON] / [OFF]	Check the main motor on or off status
[CONT:MOTO:STAT ON OFF]	[ON] / [OFF]	Turn on or turn off the main motor
[*IDN?]	[Distek 310x, serial #, Rev #]	Read the device ID information
[MEAS:RPM:CUR]	[<i>nnnnn</i>]	Check the motor current RPM speed
[MEAS:RPM:MAX]	[<i>nnnnn</i>]	Check the motor maxim RPM speed
[MEAS:RPM:MIN]	[<i>nnnnn</i>]	Check the motor minimum RPM speed
[MEAS:TEMP:CUR x]	[<i>nnnnn</i>]	Check the current temperature of beaker x
[MEAS:TEMP:MAX x]	[<i>nnnnn</i>]	Check the maxim temperature of beaker x
[MEAS:TEMP:MIN x]	[<i>nnnnn</i>]	Check the minimum temperature of beaker x
[SYST:ADDR?]	[<i>nn</i> ,!]	Read the device address
[SYST:ADDR <i>nn</i>]	[<i>nn</i> ,!] / [Invalid address?]	Set the device address to <i>nn</i>
[SYST:CALDFT]	[Cal. default set OK!]	Set the calibration values of all positions to the uniform default value
[SYST:CAL? x]	[ves-slope-intercept- lowtemp-lowvalue- hightemp-highvalue- date-time] / [Invalid beaker#?]	Read the calibration value and time information of position x

Command	Response	Function
[SYST:CALSET ves-slope-intercept-lowtemp-lowvalue-hightemp-highvalue]	[Cal. set OK!] / [Invalid cal. value?]	Set the calibration values individually
[SYST:DATE?]	[mm/dd/yyyy]	Read the system date
[SYST:DATE yyyy-mm-dd]	[Date set OK!]	Set the system date
[SYST:PWRUP]	N/A	Set the device power up
[SYST:TIME?]	[hh:mm:ss]	Read the system time
[SYST:TIME hh-mm-ss]	[Time set OK!]	Set the system time
[SYST:VSL# n]	[n !] / [Invalid beaker#?]	Set the total device position number

4

Maintenance

This chapter gives a very brief overview of how to properly maintain the Bathless Disintegration System. To ensure consistent performance a Preventive Maintenance/Operational Qualification (PM/OQ) should be conducted periodically. Contact Distek for more information.

General Information	4-2
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General Information

1. Unit should be cleaned periodically by wiping with a slightly damp cloth. Do not use any harsh chemicals or detergents.
2. Electronics require no customer attention. In the event of a malfunction, please call Distek before attempting any repairs. See the Service section on page 5-3 for more information.
3. Turn off unit and unplug power cord. Remove rear cover. Apply small amount of semi-synthetic high temperature grease to main drive post located in center of the unit. (This should be done every 6 months.) Replace cover.
4. Beaker support plates require extra care. Do not allow acids or buffers to remain on the plate for extended periods of time. WIPE THE PLATE CLEAN AFTER USE. DO NOT SCRATCH OR SCORE PAINTED SURFACE.



Do not clean plastic and rubber parts with organic solvents.



5 Troubleshooting

This chapter provides troubleshooting information to identify the most common problems and their solution.

Trouble Shooting	5-2
Error Messages.....	5-2
Service	5-3

Trouble Shooting

Error Messages



x represents the station (position) number. This value can be 1-6 depending on the unit (3106, 3104 or 3102).

Error Code #	Error Reason
Err 0	No printer connected.
Err 100	RAM allocation failed.
Err 105	The beaker cannot be raised within 10 seconds.
Err 11x	Position x temperature has been above 50.0°C for approximately 60 seconds.
Err 125	During low temperature calibration, storing the relevant values to the EEPROM failed.
Err 126	During high temperature calibration, storing the relevant values to the EEPROM failed.
Err 127	During low temperature calibration, the temperature value must be < 25.0°C. In this case, if the low set temperature is greater than ($T_{\text{high}} - 15.0^{\circ}\text{C}$), this error occurs (T_{high} is the high calibration set temperature used in the last calibration).
Err 128	During high temperature calibration, the temperature value must be $\geq 25.0^{\circ}\text{C}$. In this case, if the high set temperature is less than ($T_{\text{low}} + 15.0^{\circ}\text{C}$), this error occurs (T_{low} is the low calibration set temperature used in the last calibration).
Err 130	The printer is busy.
Err 131	The printer does not have paper.
Err 132	The printer has another error (might be specific to the printer).
Err 14x	Position x temperature rising slope is too large (i.e. the temperature is rising too fast).
Err 15x	Position x temperature increase is nearly 0.
Err 16x	Position x test duration time is set to 0.

Service

If you have a problem with the instrument or need parts information, contact the Distek Service Department by e-mail at support@distekinc.com or call our toll-free number (888)234-7835.

Items returned for repair or exchange requires an R.A. #. Please contact the Distek Service Department to obtain an R.A.

Please send the return or repair to:

Distek, Inc.
Service Department
121 North Center Drive
North Brunswick, NJ 08902
Attention: R.A. # _____

Appendix A : Spare Parts and Accessories

Part Number	Description
2800-0021	Disintegration Basket Assembly
2800-0021-DM	Basket for Agitation
2800-0029	3-tube Bolus Basket with Fluted Disks
2800-0180	Basket Cover
3010-0024	Glass Tube
3010-0360	Beaker, 1L
3250-0029	Fluted Disk, 1 each

Appendix B : Pre-Installation Consideration: Electrical Power Supply

1. Locations should provide a power supply that is capable of handling the current requirement as stated in the specifications for the unit. If multiple units will be using the same power supply, the supply must be capable of handling the combined current specification for all units.
2. Because of the extensive use of microprocessor technology, it is recommended, where possible, that 12-gauge stranded-copper wiring be used for all circuit wiring. In cases where the distance from the circuit breaker sub-panel to the outlet exceeds 500 feet (150m), 12-gauge wire is the minimum that should be used. The use of larger diameter wiring reduces the voltage drop in the wiring, helps reduce power consumption, and decreases the inductive impedance of the circuit which helps smooth voltage fluctuations.
3. In addition, if possible, an isolated ground wire should be used and the site should be wired in a 3-phase, 4-wire configuration with an approximate load balancing among the phases. In sites where many systems are being installed, the number of systems wired to each phase should be balanced as much as possible.
4. To minimize the risk of damage to a system from electrical system problems:
 - 4.1 Verify that the power wiring configuration is proper.
 - 4.2 Verify that the mains voltage (“supply” to “neutral”) is within $\pm 7\%$ of the nominal supply voltage.
 - 4.3 Verify that the voltage between “neutral” and “ground” is: less than 0.3V AC in 115V installations or less than 0.5V in 220V installations.
 - 4.4 If possible, verify the current dissipation capacity of the “ground” and the “neutral” lines in the circuit wiring.
 - 4.5 Building mains should be protected with “lightning suppressors” and, ideally, each circuit should be terminated by the appropriate “surge protection” receptacle. (In the United States, suitable receptacles are supplied by Hubbell, Inc. Alternately, a computer-grade surge-suppression accessory with the appropriate current rating can be added to existing circuits.)
 - 4.6 For those users who require protection from voltage drop-outs, short term power interruptions, and supply voltage reductions, a suitable standby Uninterruptible Power Supply (UPS) should be installed between the supply and the dissolution system.
 - 4.7 For those sites whose power quality is compromised either by the nature of the generation source or imposed fluctuations and pulses, an isolation transformer or an on-line UPS may be needed.



Although the Distek Bathless Disintegration System is designed with internal surge protection, failure to follow these recommendations may compromise the operation of the system and, should the system be damaged by power surges, lightning or other significant power fluctuations, such system damage is not covered by Distek's warranty.

Appendix C : CE Declaration of Conformity

CE DECLARATION OF CONFORMITY

NOT TRANSFERABLE

Responsible Company:	Distek, Inc. 121 North Center Dr. North Brunswick, NJ. 08902
Equipment Type & Model:	Distek Disintegration Tester: Model 3106 Model 3104 Model 3102
Equipment Classification:	Electrical equipment for measurement, control and laboratory use.
Declared Compliance & Test Standards:	EMC Directives 89/336/EEC/93/68/EEC EN 61326:1997 +A1:1998 +A2:2001 UL 61010-1: 2 nd Edition CAN/CSA C22.2 No.: 61010-1 2 nd Edition UL 61010A-2-010 IEC 61010-1/EN 61010-1 EN 61010-2-10: 2003



Jeff Brinker
Engineering Manager
March 1, 2006

Appendix D : Sample Printouts from Parallel Printer



Actual printouts may vary from samples shown.

Method Printout - All Positions



Test report shown from a 3102 (2 Position Tester).

DISTEK 3102 DISINTEGRATION SYSTEM

Test Printout

Serial Number: 31700110

LOT NUMBER: _____ BATCH NUMBER: _____

DATE: 04-02-03

TIME: 12:48:27

Vessel Test Status

Vessel	Set Temp	Duration	Start-Date&Time	End-Date&Time	Status
1	37.00	00:30	04-02-03 12:10	04-02-03 12:40	Completed
2	37.00	00:30	04-02-03 12:10	04-02-03 12:40	Completed

Vessel Test Results

Ves No.	Last	Temp Max	Min	Elapsed Time
1	36.85	37.05	36.70	00:30
2	36.90	37.10	36.75	00:30

DPM Results

	Last	Max	Min	Delta (Max-Min)
DPM	30.04	31.03	29.50	1.53

Method Printout - Individual Position



Test report shown from a 3102 (2 Position Tester).

DISTEK 3102 DISINTEGRATION SYSTEM

Test Printout

Serial Number: 31700110

LOT NUMBER: _____ BATCH NUMBER: _____

DATE: 04-02-03

TIME: 12:48:27

Vessel Test Status

Vessel	Set Temp	Duration	Start-Date&Time	End-Date&Time	Status
1	37.00	00:30	04-02-03 12:10	04-02-03 12:40	Completed

Vessel Test Results

Ves No.	Last	Temp Max	Min	Elapsed Time
----	----	----	----	----
1	36.85	37.05	36.70	00:30

DPM Results

	Last	Max	Min	Delta (Max-Min)
	----	----	----	----
DPM	30.04	31.03	29.50	1.53

Calibration Printout



Calibration data shown from a 3104 (4 Position Tester).

DISTEK 3104 DISINTEGRATION SYSTEM

Calibration Printout

Serial Number: 31700110

Operator ID: _____

DATE: 04-02-03

TIME: 12:48:27

System Calibration Report

Ves	Slope	Inter.	Lo Cal	Hi Cal	Date & Time
1	21093	9975	20.28	14252	37.0 17780 01-05-03 09:34
2	21093	9975	20.28	14252	37.0 17780 01-05-03 09:34
3	21093	9975	20.28	14252	37.0 17780 01-05-03 09:34
4	21093	9975	20.28	14252	37.0 17780 01-05-03 09:34